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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,040	12/21/2001	David S. Garvey	102258.326 US2	5280
25270	7590	02/12/2004	EXAMINER	
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 02/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,040

Applicant(s)

GARVEY ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/26/04.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

CLAIMS 13-19 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment, Declarations under 37 CFR 1.131 and Information Disclosure Statement filed January 26, 2004 has been received and entered into the application. Accordingly, the specification at page 1 has been amended; claims 8-12 have been canceled; and claims 13-19 have been added. In light of applicants' remarks and the above mentioned declarations, the rejection set forth in the previous Office action under 35 USC 102(a), based on the Place et al. patent is **withdrawn**. Also, as reflected by the attached, completed copy of form PTO-1449 (1 page), the cited references have been considered.

Clarification/Further Information Requested

In applicants' most recent response to the specification at page 2, it has been set forth that the present application "claims priority under 35 USC 120 and/or 121 to U.S. Application No. 09/354,424 filed July 16, 1999". The exact relationship, however, has not been set forth, i.e., continuation, continuation-in-part...etc.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

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Also, with regards to the listed patents at page 1 of the specification which are merely “related”, applicants should amend this section to specify that priority is not being claimed based upon these other patents.

Claim Rejection - 35 USC § 112, First Paragraph

Claims 13 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the oral or nasal administration of the claimed active agent, does not reasonably provide enablement for the broad term “administration”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is maintained for the newly presented claims for the reasons of record as set forth in the previous Office at pages 2-9, with respect only to the breadth/description of the means of administration present in applicants’ specification.

Applicants’ have offered at page 4 of their amendment that the amendments to the present claims render this rejection moot. However, because the claims read on “administering” in general and the specification teachings are not so broad, the rejection is deemed to be proper.

Claim Objection

Claims 14 and 15 are objected to as depending from a rejected base claim, but would otherwise be in condition for allowance.

Interfering Subject Matter

The Examiner has noted that applicants at page 7 of their amendment have stated that there is no longer interfering subject matter between the present claims and the claims in the US

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Patent Nos. 6,306,841, 6,165,975 and 6,031,002 because the claims in the present application and the claims in the patents are separately patentable.

The Examiner cannot agree with respect to the 6,306,841 and 6,165,975. Claim 1 of the '841 patent is directed to the treatment of sexual dysfunction in a female through specific administration means of S-nitrosothiols. Also, in claims 1, 7, 8 and 14 of the '002 patent, the elements of treating female sexual dysfunction through the administration, through various routes, of a NO donor such as S-nitrosoglutathione. Upon the finding of allowance of a claim of applicants that is "the same patentable invention" as the claims of the '841 and/or '002 patent, the Examiner will begin interference proceedings.

Accordingly, for the above reasons, the Examiner deems the claims properly rejected/objected to and none are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J. Henley III
Primary Examiner
Art Unit 1614

Feb. 04, 2004